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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 08/921,533 | 09/02/1997 | PERTTI TORMALA | 2880/27 | 9610 |
| 26646 | 7590 | 03/31/2004 | EXAMINER | |
| KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004 | | | CHANNAVAJJALA, LAKSHMI SARADA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 08/921,533 | Applicant(s) TORMALA ET AL. | |
| | Examiner Lakshmi S Channavajjala | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of amendment and response dated 12-12-03 is acknowledged.

Claims 1-6 and 8-22 are pending.

Response to Arguments

Applicant's arguments, filed 12-12-03, with respect to the rejection(s) of claim(s) 1-6 and 8-22 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claims 1-6 and 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,743,257 to Tormala et al ('257) in view of GB 2085461 (GB) or GB in view of US '257.

'257 teaches a self-reinforced surgical osteosynthesis composite material formed about the absorbable polymer or copolymer matrix which is reinforced with the absorbable reinforcement units which have the same chemical element percentage composition as the matrix has (col. 3-4). With respect to the method of manufacturing, '257 teaches mixing together a melt of the absorbable polymer or copolymer and subjecting to heat and pressure (examples and claim 12). '257 teaches the same polymeric materials such as those claimed in the instant claim 13 for preparing the matrix and the reinforcing element (examples). Figure 1 of '257 shows the arrangement of the polymeric matrix and reinforcing fibers in the surgical composite material. Instant claims do not state if the polymer matrix and the reinforcing component ii) are same or different. Accordingly, the self-reinforcing polymer of '257 meets the claimed components i) and

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ii). '257 fail to teach mixing a bioceramic or bioactive glass with the absorbable polymer of the composite material.

GB teaches composite materials for orthopedic applications comprising a polymeric material such as a polyolefin and a particulate inorganic solid such as ceramic or calcium phosphate, chalk, ash or silica (page 1 and page 2). GB teaches that the inorganic particulate material has a particle size in the range of 0.05 microns to 100 microns, which is within the instant claimed range. Further, GB teaches that the particulate material is present in an amount of 20% to 80% of the composition (page 1). GB fails to teach a polymeric matrix and reinforcing polymer as claimed in the instant invention. However, GB teaches that the particulate component of the composite is present both to reinforce the composite and to enhance stiffness. Further, GB teaches that the particulate containing composite is affixed strongly to the bone and does not get detached. Both '257 and GB teach composite material for orthopedic applications and are directed to improving the strength of the composite material. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant application to include the particulate material such as ceramic or hydroxyapatite, having a particle size between 0.05 to 100 microns, of GB in the composite of '257 comprising a polymer matrix and self-reinforcing polymer with an expectation to increase the strength of the composite material because GB teaches that the addition of particulate ceramic or calcium hydroxyapatite increases the adhesion of the composite to the bone without getting detaches and thus increasing the fatigue strength and fracture toughness. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant application to prepare a self-reinforced absorbable polymer matrix i.e., a polymer matrix that is reinforced with a polymer in the composite of GB and

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further mix with the inorganic particulate material because '257 teaches that absorbable polymers typically have lower mechanical strength than compact bone and that reinforcing the matrix with a polymer improves the initial mechanical strength, high tensile, bending or shear strength and toughness of the composite material (col. 2). The expected result is a composite material with increased adhesion upon implanting to the bone and increased strength as well as toughness.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
March 24, 2004



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600